

REMARKS

The Examiner has restricted the claims into 11 different groups, as outlined in the July 2 Office Action. However, these 11 groups encompass claims that were cancelled from the present application in the Preliminary Amendment that was filed with the application on February 10, 2004. For the Examiner's convenience, a copy of the Preliminary Amendment is attached to this response. It is further noted that the Patent Office PAIR database indicates that the Preliminary Amendment was received and entered into the record, and in a telephone interview between the Examiner and Applicants' agent, Angela Dallas Sebor on July 13, 2004, the Examiner acknowledged that he had inadvertently missed the presence of the Preliminary Amendment among the filed documents and confirmed that the Preliminary Amendment had been entered. The Examiner asked Applicants' agent to respond to the Restriction Requirement by noting these facts and to further confirm the election and address the issue of sequences, as discussed below.

Initially, Applicants note that the claims as previously amended in the Preliminary Amendment referenced above have been further amended to replace one of the ten chosen genes from the Preliminary Amendment (SEQ ID NO:14) with a different gene (SEQ ID NO:26), which is done merely to ensure that a preferred commercial embodiment is presented in the pending claims. As discussed below, to the best of the present inventors' knowledge, the genes presented in the current claims have not previously been identified as being regulated by the progesterone receptors, and particularly by the receptor isoforms or in the manner set forth in the claims.

Therefore, with regard to the restriction among Groups I-XI, Applicants elect, without traverse, to prosecute Group I (original Claims 1-25), directed to a method to identify agonist ligands of progesterone receptors. All of the pending claims in the Preliminary Amendment read on the elected invention.

With regard to item 8 of the Restriction Requirement, wherein the Examiner requires an election of a single gene from Tables 1-7, Applicants provisionally elect SEQ ID NO:10 (KIAA0040 gene), with traverse.

As discussed with the Examiner on July 13, the presentation of 10 genes in the claimed method of present divisional application is a result of the prosecution of the parent application (U.S. Application Serial No. 09/814,915), whereby the Examiner agreed in that application to

examine up to 10 genes at a time in view of arguments made against a similar restriction in the parent application. 10 genes were examined with regard to the method in the parent, and 10 additional genes are recited in the claims of this divisional application. By way of reminder, in the parent application, after a discussion among Applicants' agent, Examiner Li, and Examiner Kemmerer, and after the Examiners had further consulted with Examiner Elliot, the Examiners Li and Kemmerer proposed four options for dealing with the unusual circumstance presented by the present claims, one of which was to elect any 10 genes for further examination, which is how Applicants chose to proceed in the parent, and would choose to proceed in this and subsequent divisional applications.

As set forth in the parent application, Applicants submit that the situation at hand is described in MPEP 803.02 regarding restriction practice with respect to Markush claims. As set forth in MPEP 803.02, "unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility." In the present application, all of the genes in the present Markush group of Claim 1 (and indeed all of the recited genes from the original claims) are linked by a clear common utility (e.g., special genes for identification of agonists and antagonists of PR). In addition, it is submitted that the members of the Markush group also share a substantial structural feature that is essential to that utility; i.e., regulation of expression by PR, which infers a common structural feature. In this case, as described in MPEP 803.02, the Markush claim was used because there is no appropriate or true generic language. Applicants submit that the provisions specified in MPEP 803.02 should apply here and that the restriction between genes used in the assay is not appropriate, even if the groups are independent and distinct, as the groups are linked by the common utility and structural characteristic, and because recitation by enumeration was the only reasonable way to claim this invention.

Furthermore, given that there are 105 genes described for use in the claimed method, Applicants will still have to file a total of 11 applications to ultimately cover all of the genes, which is a significant burden on the Applicants, but is nonetheless preferable to prosecuting each and every gene individually, which would create an undue burden on and create a significant and unnecessary expense for both Applicants and the Patent Office.

Moreover, as discussed with the Examiner in the July 13 telephone interview, Applicants submit that the search and examination of the claims is not expected to be overly burdensome, because the claims are not directed to the genes themselves, but rather to the use of the genes as endpoints in an assay for the identification of progesterone receptor agonists, whereby the inventors have discovered a novel association between *progesterone receptor isoforms* and the regulation of the recited genes. Therefore, the Examiner can readily limit the search by cross-referencing the sequences against the progesterone receptor aspect of the invention. Applicants submit that prior to the present invention, to the best of Applicants' knowledge, none of the claimed genes were previously known to be regulated by progesterone receptors and moreover, none of the claimed genes had been correlated with the specific PR isoforms or the manner of gene expression as a result of PR activation (i.e., whether the gene is upregulated or downregulated) that is demonstrated by the present invention. The Applicants have recently confirmed that, to the best of their knowledge, these statements hold true for the presently claimed 10 sequences.

Finally, Applicants have already amended the claims in the Preliminary Amendment to be consistent with the form of allowed claims from the parent application, in an effort to expedite prosecution of these claims. Therefore, examination of the claims as presented is not expected to present a burden on the Examiner.

In view of the foregoing remarks, Applicants respectfully request that the Examiner withdraw the Restriction Requirement in part with respect to the genes claimed, and examine the 10 genes that are currently recited in the claims.

Respectfully submitted,

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